

REMARKS

Claims 1-3, 6-20, and 25-40 are currently pending. Claims 6, 7, 13, and 18 have been cancelled. Claim 1 has been amended to incorporate claim 18. Claim 14 has been amended to depend from claim 1. No new matter has been added by these amendments.

Claims 1-3, 6-20, 25-27, and 37 stand rejected under 35 U.S.C. §103 as unpatentable over WO 96/03113 ("WO '113") in view of Schwarz, U.S. Patent App. Pub. No. 2002/0102301 and Rouffer, U.S. Patent No. 6,221,391. The cancellation of claims 6, 7, 13, and 18 renders moot their rejection. Reconsideration of the rejection of claims 1-3, 8-12, 14-17, 19, 20, 25-27, and 27 is respectfully requested.

As amended, claim 1 is directed to a self-emulsifying drug delivery system, wherein the system comprises a mixture of from about 1 wt. % to about 4 wt. % an extremely water-insoluble, lipophilic active agent; from 5 wt. % to about 40 wt. % polyvinylpyrrolidone; from about 5 wt.% to about 35 wt.% a fatty acid; and from about 20 wt. % to about 70 wt.% a surfactant; and the polyvinylpyrrolidone has a molecular weight of from about 2,500 to about 20,000.

Applicants respectfully repeat their assertion that that the Office has not demonstrated that the claims are *prima facie* obvious, because there is no motivation whatsoever to combine the cited references.

Schwarz describes solid pharmaceutical SEDD compositions comprising a lipid phase, a surfactant system, a delivery control component, and excipients for tablet formation. An example of a suitable delivery control component is a dissolution rate regulator, which may be a polymer such as hydroxypropylmethylcellulose, hydroxyethylcellulose, hydroxypropyl cellulose, carboxymethylcellulose, polyacrylic acid, polyethylene oxide, PVP, or a natural gum or polysaccharide. Schwarz does not mention a preferred molecular weight range of the PVP, but in every example comprising PVP, Schwarz uses a PVP K-25 (Examples 1-3 and 5-7) or PVP K-90 (Example 4). These PVP's have molecular weights of 25,000 and 1200000 respectively (see, e.g., U.S. Pat. No. 6,576,677, col. 2, lines 33-41). In addition, Schwarz describes compositions having less than 10% by weight of active ingredient (see Examples 1-7).

Rouffer describes SEDD compositions comprising ibuprofen; these compositions may further comprise PVP K-12 (2000-3000 Daltons) or PVP K-17 (7000-11000 Daltons).

It is the Office's assertion that

it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add PVP having a molecular weight between 2000 and

1,500,000, in the self-emulsifying drug delivery system of WO '113] for complexing, stabilizing and aiding in the sustained release of a hydrophobic drug because Schwarz teaches that PVP is water-swellaable that forms a gel, upon dissolution of which the emulsified drug is released at a regulated rate and Rouffer suggests that PVP complexes with insoluble drugs and prevents their recrystallization.

See page 4 of instant Office action.

Contrary to the Office's suggestion, Rouffer does **not** suggest that PVP having a molecular weight in the range of 2000 to 1,500,000 Daltons would be suitable in his compositions. That very large weight range referred merely to all known PVP. Rouffer **specifically restricts** his invention to two lower weight PVP's:

In the present invention, two particular PVP's are of interest: PVP K-12 (molecular weight approximately 2000-3000 Daltons) and PVP K-17 (molecular weight approximately 7000-11,000 Daltons) which are both suitable recrystallization inhibitors.

Applicants respectfully disagree that one of ordinary skill in the art would have been motivated to combine the teachings of WO '113, Rouffer, and Schwarz. Schwarz teaches the use of high molecular weight PVP, while Rouffer teaches the use of low molecular weight PVP. Applicants respectfully assert that these contradictory teachings would, in fact, have dissuaded one of skill in the art to combine the teachings of these documents with WO '113.

In light of the foregoing, Applicants assert that the Office has not shown that claims 1-3, 8-12, 14-17, 19, 20, 25-27, and 27 are *prima facie* obvious in light of WO '113 in view of Schwarz and Rouffer. Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,



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